# PHARMACY BOARD[657]

## **Notice of Intended Action**

Twenty-five interested persons, a governmental subdivision, an agency or association of 25 or more persons may demand an oral presentation hereon as provided in Iowa Code section 17A.4(1)"b."

Notice is also given to the public that the Administrative Rules Review Committee may, on its own motion or on written request by any individual or group, review this proposed action under section 17A.8(6) at a regular or special meeting where the public or interested persons may be heard.

Pursuant to the authority of Iowa Code sections 147.76 and 155A.6B, the Board of Pharmacy hereby gives Notice of Intended Action to amend Chapter 1, "Purpose and Organization," and Chapter 3, "Pharmacy Technicians"; to adopt new Chapter 5, "Pharmacy Support Persons"; and to amend Chapter 6, "General Pharmacy Practice," Chapter 7, "Hospital Pharmacy Practice," Chapter 8, "Universal Practice Standards," Chapter 14, "Public Information and Inspection of Records," Chapter 16, "Nuclear Pharmacy Practice," Chapter 18, "Centralized Prescription Filling and Processing," Chapter 25, "Child Support Noncompliance," Chapter 31, "Student Loan Default or Noncompliance with Agreement for Payment of Obligation," Chapter 32, "Nonpayment of State Debt," and Chapter 36, "Discipline," Iowa Administrative Code.

The amendments were approved at the November 17, 2009, regular meeting of the Board of Pharmacy. In Item 10, the proposed rules in new Chapter 5 establish a registration program for pharmacy support persons, including identification of individuals required to register or exempt from registration as pharmacy support persons, timeliness of registration, the information to be provided with an application for registration, registration and renewal fees, and penalties for late registration or renewal. The rules identify the tasks that may be performed by a pharmacy support person under the direct supervision of a pharmacist and also identify tasks that may not be delegated to a pharmacy support person, place the ultimate responsibility for tasks performed by a pharmacy support person with the supervising pharmacist, identify the basis for denial of an application for registration, and identify the grounds for disciplinary action against the registration of a pharmacy support person, including the sanctions that may be imposed pursuant to disciplinary action.

Proposed amendments to Chapter 3 in Items 3 to 7 are necessary due to the establishment of the new pharmacy support person registration program in proposed Chapter 5. Identification of tasks that may be delegated to pharmacy support persons resulted in the need to amend language regarding the delegation of technical functions to pharmacy technicians to ensure that the duties and functions authorized for each group of registrants are clearly delineated.

The remaining proposed amendments in Items 11 through 18 and Items 21 through 25 amend terminology to maintain consistency in references to pharmacy support persons, authorize the pharmacist in charge of a pharmacy to identify tasks that a pharmacy support person may perform in the temporary absence of the supervising pharmacist subject to the final approval of the supervising pharmacist, and establish requirements for the utilization of pharmacy support persons in general and hospital pharmacy practice and in nuclear pharmacy practice.

Items 1, 2, 19, and 20 identify the registration of pharmacy support persons as a responsibility of the Board of Pharmacy and identify the types and format of program records that will be maintained, including designation of confidential and public records. Items 26 through 31 identify registrations issued to pharmacy support persons as subject to suspension or revocation due to nonpayment of certain debts, including nonpayment of child support, debts owed to the state of Iowa, and nonpayment of student loan obligations. Items 32 through 41 amend rules relating to disciplinary actions to ensure that registrations issued to pharmacy support persons are subject to the same rights, responsibilities, and procedures as other licenses and registrations under the Board's jurisdiction.

Requests for waiver or variance of the discretionary provisions of these rules will be considered pursuant to 657—Chapter 34.

Any interested person may present written comments, data, views, and arguments on the proposed amendments not later than 4:30 p.m. on January 5, 2010. Such written materials may be sent to Terry Witkowski, Executive Officer, Board of Pharmacy, 400 S.W. Eighth Street, Suite E, Des Moines, Iowa 50309-4688; or by E-mail to terry.witkowski@iowa.gov.

These amendments are intended to implement Iowa Code sections 147.55, 147.107, 155A.3, 155A.6A, 155A.6B, 155A.13, 155A.18, 155A.23, and 155A.33.

The following amendments are proposed.

- ITEM 1. Amend rule 657—1.1(17A) as follows:
- **657—1.1(17A) Board mission.** The board of pharmacy promotes, preserves, and protects the public health, safety, and welfare by fostering the provision of pharmaceutical care to all Iowans through the effective regulation of the practice of pharmacy, the operation of pharmacies, the appropriate utilization of pharmacy technicians and pharmacy support persons, the distribution of prescription drugs and devices, and the education and training of pharmacists.
  - ITEM 2. Amend rule 657—1.3(17A,272C) as follows:
- **657—1.3(17A,272C) Responsibilities.** The responsibilities of the board include but are not limited to: 1. to 9. No change.
- 10. Registering pharmacy support persons assisting in the nontechnical functions of the practice of pharmacy pursuant to the authority of Iowa Code chapter 155A.
- ITEM 3. Amend rule **657—3.1(155A)**, definitions of "Pharmacy technician certification" and "Supportive personnel," as follows:

"Pharmacy technician certification" or "national certification" means a certificate issued by a national pharmacy technician certification authority accredited by the NCCA attesting that the technician has successfully completed the requirements of the certification program. The term includes evidence of renewal of the national certification. "National certification," as that term relates to a nuclear pharmacy technician working exclusively in an Iowa-licensed nuclear pharmacy, shall be as defined in rule 657—16.2(155A).

"Supportive personnel Pharmacy support person" means a person, other than a licensed pharmacist, a registered pharmacist-intern, or a registered pharmacy technician, who may perform nontechnical duties assigned by the pharmacist under the pharmacist's responsibility and supervision, including delivery, billing, cashier, and clerical functions pursuant to 657—Chapter 5.

- ITEM 4. Rescind the definition of "Nuclear pharmacy technician" in rule 657—3.1(155A).
- ITEM 5. Amend subrule 3.5(2) as follows:
- **3.5(2)** Required certification effective July 1, 2010. Beginning July 1, 2010, a pharmacy technician shall acquire national certification through any NCCA-accredited pharmacy technician certification program and examination, the successful completion of which fulfills the requirement for national certification. National certification of a nuclear pharmacy technician employed solely in the practice of nuclear pharmacy shall be pursuant to certification requirements identified in 657—Chapter 16.
  - ITEM 6. Amend rule 657—3.21(155A) as follows:

# 657—3.21(155A) Delegation of technical functions.

3.21(1) <u>Technical dispensing functions</u>. A pharmacist may delegate technical dispensing functions to an appropriately trained and registered pharmacy technician, but only if the pharmacist is on site present to supervise the pharmacy technician when delegated functions are performed, except as provided in 657—subrule 6.7(2) or 657—subrule 7.6(2), as appropriate, or as provided for telepharmacy in 657—Chapter 9. The pharmacist shall provide and document the final verification for the accuracy, validity, completeness, and appropriateness of the patient's prescription or medication order prior to the delivery of the medication to the patient or the patient's representative. A pharmacy technician shall not delegate technical functions to a pharmacy support person.

- **3.21(2)** *Nontechnical functions.* A pharmacist may delegate nontechnical functions to a pharmacy technician or a pharmacy support person only if the pharmacist is present to supervise the pharmacy technician or pharmacy support person when delegated nontechnical functions are performed, except as provided in 657—subrule 6.7(2) or 657—subrule 7.6(2), as appropriate, or as provided for telepharmacy in 657—Chapter 9.
  - ITEM 7. Amend rule 657—3.22(155A) as follows:
- **657—3.22(155A) Technical functions.** At the discretion of the supervising pharmacist, technical functions which may be delegated to a pharmacy technician, a certified pharmacy technician, or a pharmacy technician trainee include, but are not limited to, the following:
- 1. Performing packaging, manipulative, or repetitive tasks relating to the processing of a prescription or medication order in a licensed pharmacy.
- 2. Accepting prescription refill authorizations communicated to a pharmacy by a prescriber or by the prescriber's office.
  - 3. Contacting prescribers to obtain prescription refill authorizations.
- 4. <u>Collecting Processing pertinent patient information, including information regarding allergies</u> and disease state.
  - 5. Entering prescription and patient information into the pharmacy computer system.
- 6. Inspecting drug supplies provided and controlled by an Iowa-licensed pharmacy <u>but located or maintained outside the pharmacy department</u>, including but not limited to drug supplies maintained in an ambulance or other emergency medical service vehicle, a long-term care facility, a hospital nursing unit, or a hospice facility.
- 7. Affixing required prescription labels upon any container of drugs sold or dispensed pursuant to the prescription of an authorized prescriber.
- 8. Prepackaging or labeling multidose and single-dose packages of drugs, including dose picks for unit dose cart or AMDS fills for hospital or long-term care facility patients.
  - ITEM 8. Amend rule 657—3.23(155A) as follows:
- **657—3.23(155A)** Tasks a pharmacy technician shall not perform. A pharmacy technician, a certified pharmacy technician, or a pharmacy technician trainee shall not:
  - 1. to 5. No change.
  - 6. Delegate technical functions to supportive personnel a pharmacy support person.
  - ITEM 9. Rescind and reserve rule 657—3.25(155A).
  - ITEM 10. Adopt the following **new** 657—Chapter 5:

# CHAPTER 5 PHARMACY SUPPORT PERSONS

- **657—5.1(155A) Definitions.** For purposes of this chapter, the following definitions shall apply:
  - "Board" means the Iowa board of pharmacy.
- "Delivery" means the transport and conveyance of a finished, securely packaged prescription order to the patient or the patient's agent.
- "Direct access" means physical access, without direct supervision by a pharmacist, to opened, unpackaged, or unsecured stock containers or prescription vials containing prescription drugs.
- "Pharmacy clerk" means a person whose duties within the pharmacy department include accessing filled prescription orders and processing payments for and delivering such orders to the patient or the patient's agent under the supervision of a pharmacist.
- "Pharmacy support person" means a person, other than a licensed pharmacist, a registered pharmacist-intern, or a registered pharmacy technician, who may perform nontechnical duties assigned by a supervising pharmacist under the pharmacist's responsibility and supervision.

"Pharmacy technician" or "technician" means a person who is employed in Iowa by a licensed pharmacy under the responsibility of an Iowa-licensed pharmacist to assist in the technical functions of the practice of pharmacy and who is registered pursuant to 657—Chapter 3.

"Secure package" means the prescription order is enclosed in tamper-evident packaging. An IV bag is considered tamper-evident packaging.

"Supervising pharmacist" means an Iowa-licensed pharmacist who is on duty in an Iowa-licensed pharmacy and who is responsible for assigning and supervising the duties performed by a pharmacy support person.

**657—5.2(155A) Purpose of registration.** A registration program for pharmacy support persons is established for the purposes of identification, tracking, and disciplinary action. The registration shall not include any determination of the competency of the registered individual. The use of pharmacy support persons to assist the pharmacist with nontechnical duties associated with the practice of pharmacy enables the pharmacist to provide pharmaceutical care to the patient.

# **657—5.3** Reserved.

# 657—5.4(155A) Registration required.

- **5.4(1)** Effective date. Beginning April 1, 2010, a pharmacy support person shall register with the board pursuant to the requirements of this chapter.
- **5.4(2)** Registration number. Each pharmacy support person registered with the board will be assigned a unique registration number.
- **5.4(3)** Original application required. Any person required to register and not previously registered with the board as a pharmacy support person shall complete an application for registration within 30 days of accepting employment in an Iowa pharmacy as a pharmacy support person. Such application shall be received in the board office before the expiration of this 30-day period.
- **5.4(4)** Employment terminated. A registered pharmacy support person who discontinues employment as a pharmacy support person shall not be required to maintain a registration and shall request cancellation of the registration as provided in rule 657—5.14(155A).
- **657—5.5(155A)** Exempt from registration. Unless a person has direct access to prescription drugs, the following shall be exempt from registration as a pharmacy support person:
  - 1. Delivery person.
  - 2. Billing clerk, including a person who processes claims for third-party payments.
  - 3. Data processing support, maintenance, or programming personnel.
- 4. Facility maintenance personnel including but not necessarily limited to cleaning, sanitation, structural, and mechanical maintenance personnel. Facility maintenance personnel escorted by a pharmacist or a certified pharmacy technician who directly supervises the maintenance person's activities within the pharmacy department shall be exempt from registration as a pharmacy support person.
- 5. Any person not directly employed by or under contract to the pharmacy, and not under the direct supervision of a pharmacist, who provides data processing, billing, or maintenance functions outside the pharmacy department.
  - 6. A registered pharmacist-intern or a registered pharmacy technician.

#### **657—5.6** Reserved.

# 657—5.7(155A) Registration application form.

- **5.7(1)** *Required information.* The application form for a pharmacy support person registration shall require the following:
- a. Information sufficient to identify the applicant including, but not limited to, name, address, date of birth, gender, and social security number;
  - b. Educational background;

- c. Work experience;
- d. Current place or places of employment;
- e. Any other information deemed necessary by the board.
- **5.7(2)** Declaration of current impairment or limitations. The applicant shall declare any current use of drugs, alcohol, or other chemical substances that in any way impairs or limits the applicant's ability to perform the duties of a pharmacy support person with reasonable skill and safety.
- **5.7(3)** History of felony or misdemeanor crimes. The applicant shall declare any history of being charged, convicted, found guilty of, or entering a plea of guilty or no contest to a felony or misdemeanor crime (other than minor traffic violations with fines under \$100).
- **5.7(4)** *History of disciplinary actions.* The applicant shall declare any history of disciplinary actions or practice restrictions imposed by a state health care professional, licensure, or registration authority.
- **5.7(5)** *Sworn signature.* The applicant shall sign the application under penalty of perjury and shall submit the application to the board with the appropriate fees pursuant to rules 657—5.9(155A) and 657—5.11(155A).

## **657—5.8** Reserved.

# 657—5.9(155A) Registration fee.

- **5.9(1)** *Initial fee.* The fee for obtaining an initial registration shall be \$30.
- **5.9(2)** Renewal fee. The renewal fee for obtaining a biennial registration shall be \$30.
- **5.9(3)** *Timeliness.* Fees shall be paid at the time the new application or the renewal application is submitted for filing.
- **5.9(4)** Form of payment. Fee payment shall be in the form of a personal check, certified or cashier's check, or money order payable to Iowa Board of Pharmacy.
- **657—5.10(155A) Registration renewal.** A pharmacy support person registration shall expire on the second last day of the birth month following initial registration. Registration shall not require continuing education for renewal.

# 657—5.11(155A) Late application.

- **5.11(1)** Fee. A person required to register or to renew the person's registration who files a late application shall pay an additional \$30 late payment fee.
- **5.11(2)** *Timeliness of initial application.* An application for initial registration shall be assessed a late payment fee if not received within the applicable period specified in rule 657—5.4(155A).
- **5.11(3)** *Timeliness of renewal application.* An application for registration renewal shall be assessed a late payment fee if not received by the expiration date of the registration. A late payment fee shall not be assessed on an expired registration if the person was not employed as a pharmacy support person during the period following expiration of the registration.

## 657—5.12 Reserved.

- **657—5.13(155A) Registration certificates.** The original registration certificate issued by the board to a pharmacy support person shall be maintained by the pharmacy support person. Verification of current registration shall be maintained in each pharmacy where the pharmacy support person is employed in that capacity and shall be available for inspection by the board.
- **657—5.14(155A) Notifications to the board.** A pharmacy support person shall report to the board within ten days a change of name, address, place of employment, or employment status.

# 657—5.15(155A) Identification of pharmacy support person.

**5.15(1)** *Name badge.* A pharmacy support person shall wear a name badge or other form of identification while on duty which clearly identifies the person as a pharmacy support person.

**5.15(2)** *Misrepresentation prohibited.* A pharmacy support person shall not, in any manner, represent himself or herself as a pharmacist, a pharmacist-intern, or a pharmacy technician.

## **657—5.16** Reserved.

- **657—5.17(155A) Tasks a pharmacy support person shall not perform.** A pharmacy support person shall not perform any of the following judgmental or technical functions. Performance of any of these tasks by a pharmacy support person shall constitute the practice of pharmacy without a license in violation of Iowa Code section 155A.7. A pharmacy support person shall not:
- 1. Provide the final verification for the accuracy, validity, completeness, or appropriateness of a filled prescription or medication order.
- 2. Conduct prospective drug use review or evaluate a patient's medication record for purposes identified in rule 657—8.21(155A).
- 3. Provide patient counseling, consultation, or patient-specific drug information; make an offer of patient counseling on behalf of the pharmacist; or accept a refusal of patient counseling from a patient or patient's agent.
- 4. Make decisions that require a pharmacist's professional judgment, such as interpreting or applying information.
- 5. Accept by oral communication any new or refill prescription authorizations communicated to a pharmacy by a prescriber or by the prescriber's office or contact a prescriber to obtain prescription refill authorizations.
- 6. Provide a prescription or drug to a patient without a pharmacist's verification as to the accuracy of the dispensed medication and without the physical presence of a pharmacist.
- 7. Package, pour, or place in a container for dispensing, sale, distribution, transfer, vending, or barter any drug which, under federal or state laws, may be sold or dispensed only pursuant to the prescription of a practitioner authorized to prescribe drugs. This prohibited task includes the addition of water or other liquid for reconstitution of oral antibiotic liquids.
- 8. Affix required prescription labels upon any container of drugs sold or dispensed pursuant to the prescription of an authorized prescriber.
- 9. Process or enter pertinent patient or prescription information, including entry of that information into the pharmacy computer system, except as provided in rule 657—5.18(155A).
- 10. Prepackage or label multidose and single-dose packages of drugs, including dose picks for unit dose cart fills for hospital or long-term care facility patients.
- 11. Check or inspect drug supplies provided and controlled by an Iowa-licensed pharmacy but located or maintained outside the pharmacy department, including but not limited to drug supplies maintained in an ambulance or other emergency medical service vehicle, a long-term care facility, a hospital nursing unit, or a hospice facility.
- 12. Reconstitute prefabricated noninjectable medication, prepare parenteral products, or compound sterile or nonsterile drug products.
- 13. Communicate, transmit, or receive patient or prescription information to or from the pharmacy for the purpose of transferring a patient's prescription between pharmacies.
- 14. Assist with or witness the destruction or wastage of controlled substances pursuant to 657—subrule 10.18(2).
- 15. Perform any of the duties identified in 657—Chapter 3 as technical functions that may be delegated to a pharmacy technician.
- **657—5.18(155A) Nontechnical pharmacy support tasks.** An appropriately trained and registered pharmacy support person may perform any of the following nontechnical functions that have been delegated to the pharmacy support person by the supervising pharmacist:
  - 1. Perform the duties of a pharmacy clerk.

- 2. Process wholesale drug orders, including the submission of orders, the receipt and processing of drug deliveries from drug wholesalers, reconciling products received with packing slips or invoices, and affixing appropriate inventory or price stickers to drug stock bottles or containers.
- 3. Perform routine clerical duties, such as filing processed, hard-copy prescriptions and other pharmacy records.
- 4. Update or change patient demographic information, excluding allergies and disease state information, in the pharmacy computer system or patient profile.
- 5. Receive from a patient the patient's request for a prescription refill, excluding the processing of the refill request.
- 6. Perform pharmacy drug inventory control duties, including checking pharmacy stock shelves for outdated drugs and assisting with annual inventory counts.
- 7. Deliver drugs to patient care areas, long-term care facilities, patient residences, or patient employment locations, excluding the restocking of automated medication distribution system components.
- 8. Perform any routine clerical or pharmacy support function not prohibited in rule 657—5.17(155A).
- 9. In nuclear pharmacy practice, perform nonjudgmental tasks under the direct supervision of a nuclear pharmacist pursuant to 657—Chapter 16.

# 657—5.19 Reserved.

- 657—5.20(155A) Training and utilization of pharmacy support persons. All Iowa-licensed pharmacies utilizing pharmacy support persons shall develop, implement, and periodically review written policies and procedures for the training and utilization of pharmacy support persons. Pharmacy policies shall specify the frequency of review. Pharmacy support person training shall be documented and maintained by the pharmacy for the duration of employment. Such policies and procedures and documentation of pharmacy support person training shall be available for inspection by the board or an agent of the board.
- **657—5.21(155A) Responsibility of supervising pharmacist.** The ultimate responsibility for the actions of a pharmacy support person working under a supervising pharmacist shall remain with the supervising pharmacist.
- **657—5.22(155A) Delegation of nontechnical functions.** A pharmacist may delegate nontechnical functions to an appropriately trained and registered pharmacy support person, but only if the pharmacist is present to supervise the pharmacy support person when delegated functions are performed, except as provided in 657—subrule 6.7(2) or 657—subrule 7.6(2), as appropriate.

## **657—5.23** Reserved.

- **657—5.24(155A) Denial of registration.** The board may deny an application for registration as a pharmacy support person for any violation of the laws of this state, another state, or the United States relating to prescription drugs, controlled substances, or nonprescription drugs or for any violation of Iowa Code chapter 124, 124A, 124B, 126, 147, 155A, or 205 or any rule of the board.
- **657—5.25(147,155A)** Unethical conduct or practice. Violation by a pharmacy support person of any of the provisions of this rule shall constitute unethical conduct or practice and may be grounds for disciplinary action as provided in rule 657—5.26(155A).
- **5.25(1)** *Misrepresentative deeds.* A pharmacy support person shall not make any statement tending to deceive, misrepresent or mislead anyone, or be a party to or an accessory to any fraudulent or deceitful practice or transaction in pharmacy or in the operation or conduct of a pharmacy.
- **5.25(2)** Confidentiality. In the absence of express consent from the patient or order or direction of a court, except where the best interests of the patient require, a pharmacy support person shall not divulge

or reveal to any person other than the patient or the patient's authorized representative, the prescriber or other licensed practitioner then caring for the patient, a licensed pharmacist, or a person duly authorized by law to receive such information the contents of any prescription or the therapeutic effect thereof or the nature of professional pharmaceutical services rendered to a patient; the nature, extent, or degree of illness suffered by any patient; or any medical information furnished by the prescriber.

- **5.25(3)** *Discrimination.* It is unethical for a pharmacy support person to unlawfully discriminate between patients or groups of patients for reasons of religion, race, creed, color, sex, age, national origin, or disease state when providing pharmaceutical services.
- **5.25(4)** *Unethical conduct or behavior.* A pharmacy support person shall not exhibit unethical behavior in connection with the pharmacy support person's pharmacy employment. Unethical behavior shall include, but is not limited to, the following acts: verbal abuse, coercion, intimidation, harassment, sexual advances, threats, degradation of character, indecent or obscene conduct, and theft.

# 657—5.26(155A) Discipline of pharmacy support persons.

- **5.26(1)** *Violations*. The board may impose discipline for any violation of the laws of this state, another state, or the United States relating to prescription drugs, controlled substances, or nonprescription drugs or for any violation of Iowa Code chapter 124, 124A, 124B, 126, 147, 155A, or 205 or any rule of the board.
  - **5.26(2)** Sanctions. The board may impose the following disciplinary sanctions:
  - a. Revocation of a pharmacy support person registration.
- b. Suspension of a pharmacy support person registration until further order of the board or for a specified period.
  - c. Nonrenewal of a pharmacy support person registration.
- d. Prohibition, permanently, until further order of the board, or for a specified period, from engaging in specified procedures, methods, or acts.
  - e. Probation.
  - f. Imposition of civil penalties not to exceed \$25,000.
  - g. Issuance of citation and warning.
  - h. Such other sanctions allowed by law as may be appropriate.

These rules are intended to implement Iowa Code sections 147.55, 155A.3, 155A.6B, 155A.18, and 155A.23.

## ITEM 11. Amend rule 657—6.2(155A) as follows:

- **657—6.2(155A) Pharmacist in charge.** One professionally competent, legally qualified pharmacist in charge in each pharmacy shall be responsible for, at a minimum, the following:
  - 1. to 8. No change.
  - 9. Training pharmacy technicians and supportive personnel pharmacy support persons.
  - 10. to 16. No change.
  - ITEM 12. Amend subrule 6.7(2) as follows:
- **6.7(2)** Temporary absence of pharmacist. In the temporary absence of the pharmacist, only the pharmacist in charge may designate persons pharmacy technicians or pharmacy support persons who may be present in the prescription department to perform technical and or nontechnical functions, respectively, designated by the pharmacist in charge. Activities identified in subrule 6.7(3) may not be performed during such temporary absence of the pharmacist. A temporary absence is an absence of short duration not to exceed two hours. In the absence of the pharmacist, the pharmacy shall notify the public that the pharmacist is temporarily absent and that no prescriptions will be dispensed until the pharmacist returns.

# ITEM 13. Amend rule 657—7.2(155A) as follows:

- **657—7.2(155A) Pharmacist in charge.** One professionally competent, legally qualified pharmacist in charge in each pharmacy shall be responsible for, at a minimum, the items identified in this rule. A part-time pharmacist in charge has the same obligations and responsibilities as a full-time pharmacist in charge. Where 24-hour operation of the pharmacy is not feasible, a pharmacist shall be available on an "on call" basis. The pharmacist in charge, at a minimum, shall be responsible for:
  - 1. to 8. No change.
  - 9. Training pharmacy technicians and supportive personnel pharmacy support persons.
- 10. Ensuring adequate and appropriate pharmacist oversight and supervision of pharmacy technicians and supportive personnel pharmacy support persons.
  - 11. to 16. No change.
  - ITEM 14. Amend subrule 7.6(2) as follows:
- **7.6(2)** Access when pharmacist absent. When the pharmacist is absent from the facility, the pharmacy is closed. Policies and procedures shall be established that identify who will have access to the pharmacy when the pharmacy is closed and the procedures to be followed for obtaining drugs, devices, and chemicals to fill an emergent need during the pharmacist's absence.
- a. The pharmacist in charge may designate pharmacy technicians or pharmacy support persons who may be present in the pharmacy to perform technical and or nontechnical functions, respectively, designated by the pharmacist in charge. Activities identified in paragraph "d" of this subrule may not be performed when the pharmacy is closed.
- b. If the pharmacist in charge has authorized the presence in the pharmacy of a pharmacy technician or a pharmacy support person to perform designated functions when the pharmacy is closed, the only a pharmacy technician may assist another authorized, licensed health care professional to locate a drug or device pursuant to an emergent need. The pharmacy technician or the pharmacy support person may not dispense or deliver the drug, chemical, or device to the licensed health care professional. The licensed health care professional shall comply with established policies and procedures for obtaining drugs, devices, and chemicals when the pharmacy is closed. The licensed health care professional shall not ask or expect the pharmacy technician or the pharmacy support person to verify that the appropriate drug, chemical, or device has been obtained from the pharmacy.
- c. A pharmacy technician <u>or a pharmacy support person</u> who is present in the pharmacy when the pharmacy is closed shall prepare and maintain in the pharmacy a log identifying each period of time that the <u>pharmacy</u> technician <u>or pharmacy support person</u> worked in the pharmacy while the pharmacy was closed and identifying each activity performed during that time period. Each entry shall be dated and each daily record shall be signed by the pharmacy technician <u>or pharmacy support person</u> who prepared the record. The log shall be periodically reviewed by the pharmacist in charge.
- d. Activities which shall not be performed by a pharmacy technician or a pharmacy support person when the pharmacist is absent from the facility include:
- (1) Dispensing, delivering, or distributing any prescription drugs or devices to patients or others, including health care professionals, prior to pharmacist verification. Verification by a nurse or other licensed health care professional shall not supplant verification by a pharmacist.
- (2) Providing the final verification for the accuracy, validity, completeness, or appropriateness of a filled prescription or medication order.
- (3) Conducting prospective drug use review or evaluating a patient's medication record for purposes identified in rule 657—8.21(155A).
  - (4) Providing patient counseling, consultation, or drug information.
- (5) Making decisions that require a pharmacist's professional judgment such as interpreting or applying information.
- (6) Preparing compounded drug products for immediate administration by other hospital staff or health care professionals without verification by a pharmacist.

- ITEM 15. Amend subrule 8.3(2) as follows:
- **8.3(2)** Practice functions. The pharmacist is responsible for all functions performed in the practice of pharmacy. The pharmacist maintains responsibility for any and all delegated functions including functions delegated to pharmacist-interns, pharmacy technicians, and other supportive personnel pharmacy support persons.
  - ITEM 16. Amend subrule 8.4(3) as follows:
- **8.4(3)** Temporary or intermittent pharmacy staff. The pharmacy shall maintain a log of all pharmacists, pharmacist-interns, and pharmacy technicians, and pharmacy support persons who have worked at that pharmacy and who are not regularly staffed at that pharmacy. Such log shall include the dates and shifts worked by each pharmacist, pharmacist-intern, and pharmacy technician, and pharmacy support person and shall be available for inspection and copying by the board or its representative for a minimum of two years following the date of the entry.
  - ITEM 17. Amend rule 657—8.14(155A) as follows:
- **657—8.14(155A)** Training and utilization of pharmacy technicians or pharmacy support persons. All Iowa-licensed pharmacies utilizing pharmacy technicians or pharmacy support persons shall develop, implement, and periodically review written policies and procedures for the training and utilization of pharmacy technicians and pharmacy support persons appropriate to the practice of pharmacy at that licensed location. Pharmacy policies shall specify the frequency of review. Technician Pharmacy technician and pharmacy support person training shall be documented and maintained by the pharmacy for the duration of employment. Policies and procedures and documentation of pharmacy technician and pharmacy support person training shall be available for inspection by the board or an agent of the board.
  - ITEM 18. Amend subrule 8.35(3) as follows:
- **8.35(3)** Application form. Application for licensure and license renewal shall be on forms provided by the board. The application for a pharmacy license shall require an indication of the pharmacy ownership classification. If the owner is a sole proprietorship (100 percent ownership), the name and address of the owner shall be indicated. If the owner is a partnership or limited partnership, the names and addresses of all partners shall be listed or attached. If the owner is a corporation, the names and addresses of the officers and directors of the corporation shall be listed or attached. Any other pharmacy ownership classification shall be further identified and explained on the application. The application form shall require the name, signature, and license number of the pharmacist in charge. The names and license numbers of all pharmacy technicians and pharmacy support persons working in the pharmacy, and the average number of hours worked by each pharmacist, and each pharmacy technician, and pharmacy support person shall be listed or attached. Additional information may be required of specific types of pharmacy license applicants. The application shall be signed by the pharmacy owner or the owner's, partnership's, or corporation's authorized representative.
  - ITEM 19. Amend subrule 14.14(14) as follows:
- **14.14(14)** *Notifications to the board.* These records contain reports of theft or loss of controlled substances; of pharmacy or drug wholesaler openings, closings, and changes of ownership, location, or responsible person; of the sale or transfer of prescription drugs including controlled substances; of disasters, accidents, or emergencies affecting drugs; and of pharmacists', pharmacist-interns', and pharmacy technicians', and pharmacy support persons' names, addresses, or employment changes. This information is collected by the board pursuant to the authority granted in Iowa Code sections 155A.6, 155A.6A, 155A.6B, and 155A.19 and is stored on paper, electronically, and in computer.
  - ITEM 20. Adopt the following **new** subrule 14.14(17):
- **14.14(17)** *Pharmacy support person records.* These records contain information about pharmacy support persons who are registered with the board. This information is collected by the board pursuant to the authority granted in Iowa Code chapter 155A and is stored on paper, electronically, and in computer.

- ITEM 21. Renumber subrules **16.4(4)** to **16.4(10)** as **16.4(5)** to **16.4(11)**.
- ITEM 22. Adopt the following **new** subrule 16.4(4):
- **16.4(4)** *Pharmacy support persons*. A pharmacy support person shall register with the board pursuant to the registration requirements of 657—Chapter 5. Alternatively, a pharmacy support person may register with the board as a pharmacy technician pursuant to the registration and national certification requirements of 657—Chapter 3.
  - ITEM 23. Adopt the following **new** rule 657—16.7(155A):
- **657—16.7(155A) Training and utilization of pharmacy support persons.** Nuclear pharmacies utilizing pharmacy support persons shall develop, implement, and periodically review written policies and procedures for the training and utilization of pharmacy support persons. Pharmacy policies shall specify the frequency of review. Pharmacy support person training shall be documented and maintained by the pharmacy for the duration of employment. Such policies and procedures and documentation of pharmacy support person training shall be available for inspection by the board or an agent of the board.
  - ITEM 24. Amend paragraph 18.3(2)"e" as follows:
- *e*. Pharmacies shall comply with Iowa requirements for supervision of pharmacy technicians <u>and</u> pharmacy support persons.
  - ITEM 25. Amend rule **657—25.1(252J)**, definition of "License," as follows:
- "License" means a license to practice pharmacy, a registration to practice as a pharmacist-intern, a registration to practice as a pharmacy technician, a registration to practice as a pharmacy support person, or a registration to possess, prescribe, dispense, administer, distribute, or otherwise handle controlled substances under Iowa Code chapter 124.
  - ITEM 26. Amend subrule 25.3(5) as follows:
- **25.3(5)** Reinstatement following license suspension or, revocation, or denial of renewal. A licensee shall pay all board fees required for license renewal or license reinstatement, and all continuing education requirements shall be met, before a license will be reinstated after the board has suspended a license pursuant to the Act. A licensee whose license to practice pharmacy has been revoked shall complete the examination components as indicated in <u>rule</u> 657—2.10(155A) and shall pay all required examination fees pursuant to <u>rule</u> 657—2.2(147). A licensee whose registration to practice as a pharmacist-intern, or as a pharmacy technician, or as a pharmacy support person or whose registration to handle controlled substances under Iowa Code chapter 124 has been revoked shall complete application and pay all board fees required for new registration.
  - ITEM 27. Amend rule 657—31.1(261), definition of "License," as follows:
- *"License"* means a license to practice pharmacy, a registration to practice as a pharmacist-intern, a registration to practice as a pharmacy technician, a registration to practice as a pharmacy support person, or a registration to possess, prescribe, dispense, administer, distribute, or otherwise handle controlled substances under Iowa Code chapter 124.
  - ITEM 28. Amend subrule 31.3(5) as follows:
- **31.3(5)** Reinstatement following license suspension or revocation, or denial of renewal. All board fees required for license renewal or license reinstatement shall be paid by licensees, and all continuing education requirements shall be met, before a license will be renewed or reinstated after the board has suspended a license pursuant to the Act. A licensee whose license to practice pharmacy has been revoked shall complete the examination components as indicated in rule 657—2.10(155A) and shall pay all required examination fees pursuant to rule 657—2.2(147). A licensee whose registration to practice as a pharmacist-intern, or as a pharmacy support person or whose registration to handle controlled substances under Iowa Code chapter 124 has been revoked shall complete application and pay all board fees required for new registration.

# ITEM 29. Amend rule **657—32.1(272D)**, definition of "License," as follows:

*"License"* means a license to practice pharmacy, a registration to practice as a pharmacist-intern, a registration to practice as a pharmacy technician, a registration to practice as a pharmacy support person, or a registration to possess, prescribe, dispense, administer, distribute, or otherwise handle controlled substances under Iowa Code chapter 124.

# ITEM 30. Amend subrule 32.3(5) as follows:

**32.3(5)** Reinstatement following license suspension, revocation, or denial of renewal. All board fees required for license renewal or license reinstatement shall be paid by the licensee and all continuing education requirements shall be met before a license will be renewed or reinstated after the board has suspended a license pursuant to the Act. A licensee whose license to practice pharmacy has been revoked shall complete the examination components as indicated in rule 657—2.10(155A) and shall pay all required examination fees pursuant to rule 657—2.2(155A). A licensee whose registration to practice as a pharmacist-intern, or as a pharmacy support person or whose registration to handle controlled substances under Iowa Code chapter 124 has been revoked shall complete an application and pay all board fees required for new registration.

# ITEM 31. Amend paragraph **36.1(2)"h"** as follows:

*h*. Order a pharmacist, pharmacist-intern, or pharmacy technician, or pharmacy support person to undergo a physical or mental examination.

# ITEM 32. Amend paragraphs 36.1(4)"a," "i," "l," "v," "aa" and "ab" as follows:

- a. Fraud in procuring a license. Fraud in procuring a license includes but is not limited to an intentional perversion of the truth in making application for a license to practice pharmacy, to operate a pharmacy doing business in this state, or to operate as a wholesale drug distributor doing business in this state, or in making application for a registration to practice as a pharmacist-intern, or a pharmacy support person. It includes false representations of a material fact, whether by word or conduct, by false or misleading allegations, or by concealment of that which should have been disclosed when making application, or attempting to file or filing with the board any false or forged diploma, certificate, affidavit, identification, or qualification in making application for a license or registration in this state.
- *i.* Willful or repeated violations of the provisions of Iowa Code chapter 147 or Iowa Code chapter 272C. Willful or repeated violations of these Acts include, but are not limited to, a pharmacist's, pharmacist-intern's, or pharmacy technician's, or pharmacy support person's intentionally or repeatedly violating a lawful rule or regulation promulgated by the board of pharmacy or the state department of public health, violating a lawful order of the board in a disciplinary hearing, or violating the provisions of Title IV (Public Health) of the Code of Iowa.
- *l.* Knowingly aiding, assisting, procuring, or advising another person to unlawfully practice pharmacy or to unlawfully perform the functions of <u>a pharmacist-intern</u>, a pharmacy technician <del>or a pharmacist-intern</del>, or a pharmacy support person.
- v. Practicing pharmacy without an active and current Iowa pharmacist license, operating a pharmacy without a current pharmacy license, operating a prescription drug wholesale facility without a current wholesale drug license, practicing as a pharmacist-intern without a current pharmacist-intern registration, or assisting a pharmacist with technical functions associated with the practice of pharmacy without a current pharmacy technician registration except as provided in rule 657—3.3(155A), introductory paragraph, or assisting a pharmacist with nontechnical functions associated with the practice of pharmacy without a current pharmacy support person registration.
- aa. Employing or continuing to employ as a practicing pharmacist any person whose Iowa pharmacist license is not current and active, or employing or continuing to employ a person to assist a pharmacist with technical functions associated with the practice of pharmacy who is not currently registered as a pharmacy technician except as provided in rule 657—3.3(155A), introductory paragraph, or employing or continuing to employ a person to assist a pharmacist with nontechnical functions associated with the practice of pharmacy who is not currently registered as a pharmacy support person.

- *ab.* Retaliatory action. Retaliating against a pharmacist, pharmacist-intern, or a pharmacy technician, or pharmacy support person for making allegations of illegal or unethical activities, making required reports to the board, or cooperating with a board investigation or survey.
  - ITEM 33. Amend subrule 36.2(2) as follows:
- **36.2(2)** Reporting of judgments or settlements. Each licensee or registrant shall report to the board every adverse judgment in a malpractice action to which the pharmacy, pharmacist, pharmacist-intern, of pharmacy technician, or pharmacy support person is a party, and every settlement of a claim alleging malpractice. The report must be filed within 30 days from the date of the judgment or settlement.
  - ITEM 34. Amend subrule 36.2(3) as follows:
- **36.2(3)** Reporting of acts or omissions. Each licensee or registrant having firsthand knowledge of acts or omissions set forth in subrule 36.1(4) shall report to the board within 30 days of initially acquiring the information those acts or omissions committed by another person licensed to practice pharmacy or registered to practice as a pharmacist-intern, of as a pharmacy technician, or as a pharmacy support person. The report shall include the name and other available information identifying the licensee or registrant and the date, time, and place of the incident.
  - ITEM 35. Amend rule 657—36.4(17A,124,124B,126,147,155A,272C) as follows:
- **657—36.4(17A,124,124B,126,147,155A,272C) Disciplinary proceedings.** The proceeding for revocation, suspension, or other disciplinary sanctions against a pharmacy license, a wholesale drug license, a pharmacy technician registration, a pharmacy support person registration, a pharmacist-intern registration, or a license to practice pharmacy, or the denial of or refusal to issue or renew a license or registration, or the suspension, denial, or revocation of a permit to handle precursor substances shall be substantially in accordance with the procedures set forth in 657—Chapter 35 and these rules, which are in addition to the procedures stated in Iowa Code sections 147.58 et seq., and 155A.16.
  - ITEM 36. Amend rule 657—36.11(272C) as follows:
- **657—36.11(272C) Board decision.** The board's decision and order to discipline a licensee, registrant, or permittee, or to revoke or suspend a license to practice pharmacy, a wholesale drug license, a license to operate a pharmacy, a registration to practice as a pharmacist-intern, or as a pharmacy technician, or a pharmacy support person, or a permit to handle precursor substances, shall remain in force and effect until the appeal is finally determined and disposed of upon its merit unless the board grants a stay of its decision as provided for in rule 657—35.28(17A).
- ITEM 37. Amend rule 657—36.13(17A,124B,147,155A,272C), introductory paragraph, as follows:
- **657—36.13(17A,124B,147,155A,272C) Reinstatement.** Any person whose license to practice pharmacy or to operate a pharmacy or whose wholesale drug license or permit to handle precursor substances or whose <u>pharmacist-intern registration</u>, pharmacy technician registration of <u>pharmacist-intern registration</u>, or pharmacy support person registration has been revoked or suspended shall meet the following eligibility requirements for reinstatement:
  - ITEM 38. Amend rule 657—36.15(17A,124B,147,155A,272C) as follows:
- **657—36.15(17A,124B,147,155A,272C) Voluntary surrender of a license, permit, or registration.** The voluntary surrender of a license to practice pharmacy, a license to operate a pharmacy, a wholesale drug license, a permit to handle precursor substances, a pharmacy technician registration, a pharmacy support person registration, or a pharmacist-intern registration shall be considered a revocation of license, permit, or registration. A request for reinstatement shall be handled under the terms established by rule 657—36.13(17A,124B,147,155A,272C).

- ITEM 39. Amend rule 657—36.17(155A,272C), introductory paragraph, as follows:
- **657—36.17(155A,272C) Order for mental or physical examination.** A pharmacist, pharmacist-intern, or pharmacy technician, or pharmacy support person who is licensed or registered by the board is, as a condition of licensure or registration, under a duty to submit to a mental or physical examination within a time period specified by order of the board. Such examination may be ordered upon a showing of probable cause and shall be at the expense of the pharmacist, pharmacist-intern, or pharmacy technician, or pharmacy support person.
  - ITEM 40. Amend subrule 36.17(1) as follows:
- **36.17(1)** Content of order. A board order for mental or physical examination shall include the following items:
- *a.* A description of the type of examination to which the pharmacist, pharmacist-intern, or pharmacy technician, or pharmacy support person must submit.
- b. The name and address of the examiner or treatment facility that the board has identified to perform the examination on the pharmacist, pharmacist-intern, or pharmacy technician, or pharmacy support person.
- c. The time period in which the pharmacist, pharmacist-intern, or pharmacy support person must schedule the required examination.
- d. The amount of time in which the pharmacist, pharmacist-intern, or pharmacy technician, or pharmacy support person is required to complete the examination.
- *e.* A requirement that the pharmacist, pharmacist-intern, or pharmacy technician, or pharmacy support person cause a report of the examination results to be provided to the board within a specified period of time.
- f. A requirement that the pharmacist, pharmacist-intern, or pharmacy technician, or pharmacy support person communicate with the board regarding the status of the examination.
- g. A provision allowing the pharmacist, pharmacist-intern, or pharmacy technician, or pharmacy support person to request additional time to schedule or complete the examination or to request that the board approve an alternative examiner or treatment facility. The board shall, in its sole discretion, determine whether to grant such a request.